FORM APPROVED
OMB NO. 0579-0213
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EXP DATE 01/31/2006

GUIDANCE DOCUMENT FOR REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN IN A CLINICAL OR DIAGNOSTIC LABORATORY

INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188; June 12, 2002) requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (7 CFR 331 and 9 CFR 121).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection. This form (APHIS/CDC Form 4) is designed to assist entities in complying with this legal obligation.

Clinical or diagnostic laboratories and other entities that have identified the following select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by regulation (7 CFR 331, 9 CFR 121, and 42 CFR 73) to contact APHIS (telephone: 301-734-5960, facsimile: 301-734-3652) or CDC (telephone (404-498-2255), facsimile (404-498-2265), or e-mail (lrsat@cdc.gov)) immediately: African horse sickness virus, African swine fever virus, Avian influenza virus (highly pathogenic), *Bacillus anthracis*, Botulinum neurotoxins, Bovine spongiform encephalopathy agent, *Brucella melitensis*, Classical swine fever virus, Foot-and-Mouth disease virus, *Francisella tularensis*, Ebola viruses, Hendra virus, Lassa fever virus, *Liberobacter africanus, Liberobacter asiaticus,* Marburg virus, Newcastle disease virus (velogenic), Nipah virus, *Peronosclerospora philippinensis, Ralstonia solanacearum* race 3, biovar 2, Rift Valley fever virus, Rinderpest virus, *Schlerophthora rayssiae* var *zeae,* South American Hemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Swine vesicular disease virus, *Synchytrium endobioticum,* Variola major virus (Smallpox virus), Variola minor (Alastrim), Venezuelan equine encephalitis virus, *Xanthomonas oryzae, Xylella fastidiosa* (citrus variegated chlorosis strain), and *Yersinia pestis*.

INSTRUCTIONS

Diagnosis and Verification

Within seven calendar days after identification, the select agent or toxin contained in a specimen presented for diagnosis or verification is transferred in accordance with 42 CFR 73.16 or 9 CFR 121.16, destroyed on-site by a recognized sterilization or inactivation process, or retained if the entity is currently registered for the select agent and toxin identified.

1. Completes sections 1, 2 or 3, and 5.
2. Section 5 may require "Report of Transfer of Select Agents and Toxins" form (APHIS/CDC Form 2) to be completed in addition to this form if the entity transfers the select agent or toxin. A completed APHIS/CDC Form 2 must be submitted to APHIS or CDC for approval prior to transfer select agents or toxins to a registered entity.
3. Section 3 of the form allows for bi-weekly reporting by veterinary diagnostic entities that identify select agents or toxins in areas where the select agent is endemic or during outbreaks. An entity may request bi-weekly reporting by submitting a request in writing to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737 or by faxing it to 301-734-3652.
4. A copy of each completed form must be kept for three years.

Proficiency testing

Within 90 calendar days of receipt, the select agent or toxin contained in a specimen presented for proficiency testing is transferred in accordance with 42 CFR 73.16 or 9 CFR 121.16, destroyed on-site by a recognized sterilization or inactivation process, or retained if the entity is currently registered for the select agent and toxin identified.

1. Completes sections 1, 4, and 5.
2. Section 5 may require "Report of Transfer of Select Agents and Toxins" form (APHIS/CDC Form 2) to be completed in addition to this form if the entity transfers the select agent or toxin. A completed APHIS/CDC Form 2 must be submitted to APHIS or CDC for approval prior to transfer select agents or toxins to a registered entity.
3. A copy of each completed form must be kept for three years

NOTE: For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the APHIS at (301) 734-5960 or CDC at (404) 498-2255. This guidance document and form are also available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html or http://www.cdc.gov/od/sap.

WHERE TO SEND THE COMPLETED FORM

1. Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

2. Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

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Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The form must be signed and submitted to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737 or Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

Legal name of entity:		Entity registration number (*if applicable*):		
Address (NOT a post office address):		City:	State:	Zip Code:
Name of facility director or Responsible Official:	Title:	Telephone:	FAX:	E-mail:
Address (If different; NOT a post office address):		City:	State:	Zip Code:
Select agent or toxin being reported:		Name of facility supervisor (if applicable):		
Name and strain designation of select agent (if known) / toxin:		Facility Identification Number:		
Provide facility identification number and any data regarding molecular, phenotypic, or morphological characterization of select agent(s) or toxin(s):				
Location where work with specimens was conducted: Building: Room:		Biosafety level of laboratory or PPQ containment designation:		

SECTION 2 –TO BE COMPLETED FOR SELECT AGENTS AND TOXINS FROM CLINICAL/DIAGNOSTIC TESTING

INFORMATION ON AGENT/ TOXIN

Source of select agent isolate(s):

- ☐ Clinical or diagnostic specimen (Specify from which species): _____
  - ☐ Specimen type: ☐ Blood ☐ Tissue ☐ Other (specify): _____
- ☐ Environmental sample (specify type): _____
- ☐ Isolate (Specify name, address, and phone number of laboratory that sent isolate): ___ _____
  - ☐ Source of Isolate: ☐ Blood ☐ Tissue ☐ Plants ☐ Other (specify): _____
- ☐ Other (specify): _____

INFORMATION ON CLINICAL CASE FROM WHICH THE SELECT AGENT OR TOXIN WAS OBTAINED

Name of person most familiar with the case:		Telephone:
Description of the disease:		
Number of isolates:	Date of onset:	How diagnosis was made:
Laboratory that identified select agent or toxin: (Required field)		Name, address and phone of laboratory director: (Required field)

SECTION 3 –INFORMATION ON DIAGNOSTIC CASES FROM WHICH SELECT AGENTS AND TOXINS WAS OBTAINED (OUTBREAK/ENDEMIC AREAS)		
Name of person most familiar with the case:		Telephone:
Description of the disease:		
Identification date of index case:	Number of cases (bi-weekly total):	How diagnosis was made:
Laboratory that identified select agent or toxin: (Required field)	Name, address and phone of laboratory director: (Required field)	

SECTION 4 –TO BE COMPLETED FOR SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING	
Entity that you received select agent or toxin from: ☐ College of American Pathologists ☐ Registered entity (Name, CDC or APHIS registration number):_____ _____ ☐ Other (Explain):	Date received:
Name of laboratory test that proficiency test was designed to assess: Amount of original specimen retained by sending facility:	

SECTION 5 –TO BE COMPLETED BY ALL ENTITIES	
INFORMATION ON FINAL DISPOSITION OF SELECT AGENTS AND TOXINS	
Date(s) select agent or toxin was identified:	Amount of agent / toxin transferred, destroyed, or retained:
Disposition of select agent or toxin after identification: ☐ Transferred to a registered entity (give name, CDC or APHIS entity registration number, date, and CDC or APHIS authorization Number):_____ Note: Entities must complete "Report Of Transfer Of Select Agents And Toxins" form (APHIS/CDC Form 2) in addition to this section. ☐ Destroyed on site If destroyed on site: Date select agent was destroyed: _____ Method of destruction: _____ ☐ Retained ☐ Other (Provide detailed explanation):	
Is this source expected to provide additional specimens? ☐ No ☐ Yes	Anticipated quantity of specimens to be received:
Anticipated time period to receive specimen (give estimated end date):	

I certify that all select agents and toxins isolated by this entity have been retained, transferred or disposed of according to all Federal, State and local regulations. I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Laboratory Director: _____ Typed or printed name: _____

Date: _____

Public reporting burden: Public reporting burden of providing this information is estimated to average1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).